



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S) : Yung-Chi Cheng, et al.
SERIAL NO. : 10/586,822
FILED §371 : October 13, 2006
FOR : Compounds and Methods to Increase Anti-P-Glycoprotein Activity of
Baicalien By Alkylation of the A Ring
GROUP ART UNIT : 1625
Examiner : Bernard I.Dentz

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia, 22313-1450

**Election of Invention in Response
to Restriction Requirement**

In response to the Examiner's correspondence dated July 30, 2009, pursuant to the Examiner's restriction requirement in the above-referenced patent application, Applicants provisionally elect with traverse to prosecute an invention of the present application according to invention group VI, claims 37-48, drawn to a method of facilitating or enhancing the bioavailability of another bioactive agent or drug. Applicant further provisionally elects with traverse a single species wherein R⁵ is methyl, R⁶ is propyl, R⁷ is propyl and R⁸ is H. It is noted that because the invention is directed to methods which utilize a genus of compounds based upon a single pharmacophore upon which a number of substituents are appended, unity of invention of the entire genus set forth in the elected claims is established. Consequently, Applicants request that the Examiner withdraw the requirement for an election of species.

In the present application, in claims 37-48 of elected invention group VI, all of the claimed compounds, are structural analogs of the central pharmacophore having a phenyl group appended thereto. All of structures which are set forth in claims 37-48 have an identical nucleus and a common utility (enhancing bioavailability), which provides a **unity of invention** for purposes of further prosecution.

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Y03-097USNat

It is well settled that claims to compounds all having an identical nucleus with a larger variety of substituents, where all of the compounds have a common utility, are part of a single invention. The alleged burden of searching the invention in different fields of search and different search classifications plays absolutely no role in the determination of unity *vel non*. See, for example, *In re Harnisch*, 206 USPQ 300 (CCPA, 1980). The claimed compounds **must** be considered as a whole, and not separately by the different substituents on the common central nucleus. There is a unity of invention based upon the identity of the central nucleus in all compounds, especially if all of the compounds have a common utility and function and, therefore, belong to a common, recognized *genus*, and have a community of properties. See, *ex parte Brouard*, 201 USPQ 538 (Bd. App., 1976).

In the present case, all of the claimed compounds have a common utility which is inherent to the claims (enhancing bioavailability). It is noted here that the determination of unity of invention does not require that there be a community of properties (although in the present application and claimed invention group, this happens to be the case), as long as the covered compounds have a common nucleus which would exhibit certain characteristics. See, *ex parte Taylor*, 167 USPQ 637 (Bd. App., 1969).

Thus, based upon the foregoing, the law is unequivocal that as long as all of the compounds in the claims have the same common nucleus, they represent a single invention *regardless of the number and type of substituents on that common nucleus* and the alleged burden of searching the invention in different fields of search. It is also clear that different search classifications play no role in the determination of unity of invention under the law. It is respectfully submitted that a species restriction requirement in the present application would be improper and Applicants respectfully request the Examiner to issue a first office action or a notice of allowance on the merits without such further restriction.

Notwithstanding Applicants' species election, Applicants respectfully traverse the

Examiner's requirement for restriction in its entirety. Applicants respectfully request the Examiner reconsider his restriction requirement in its entirety. Applicants respectfully submit that prosecution of all of originally filed claims without regard to the imposed restriction will allow the Examiner to examine all claims without being subjected to an undue burden as discussed hereinbelow.

According to M.P.E.P. §803, restriction by the Examiner of patentably distinct inventions is proper if the claimed inventions are independent and a *serious burden* would be placed on the Examiner if restriction was not required. Applicant respectfully submits that the presentation of the originally filed claims would not place such a serious burden on the Examiner as to require restriction. All of the originally restricted claims are directed to patentably distinct, but related methods which would not impose a heavy burden of examination on the part of the Examiner.

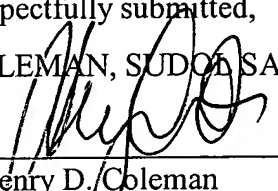
Thus, it is Applicants' view that any search the Examiner would need to conduct in examining the instant application of all the claims would not be unduly burdensome. That would not be to say that the examination would not be rigorous or even time-consuming, but that such effort would not meet the requirements of MPEP§803. It is respectfully submitted that the examination of all of the originally filed claims in the instant application would not place such a serious burden on the Examiner as to require restriction.

Applicants understand the general policy considerations for the Patent Office's requirement for restriction in certain instances. In this instance, however, those considerations do not weigh in favor of restricting the inventions here. In determining the appropriateness of restriction, one must also consider the countervailing consideration that, in each instance, Applicants wish the Patent Office examine their patent application with a certain degree of "administrative efficiency" and wish to have patent claims issue which reflect the breadth of their invention.

Applicants respectfully submit that the originally filed claims are sufficiently narrow to allow the Examiner to determine patentability without being subjected to the serious burden referred to in M.P.E.P. §803. Consequently, Applicant respectfully requests that the Examiner withdraw the restriction requirement in its entirety.

The Examiner is cordially requested to call the undersigned attorney if the Examiner believes that a telephonic discussion may materially advance the prosecution of the instant application in any way.

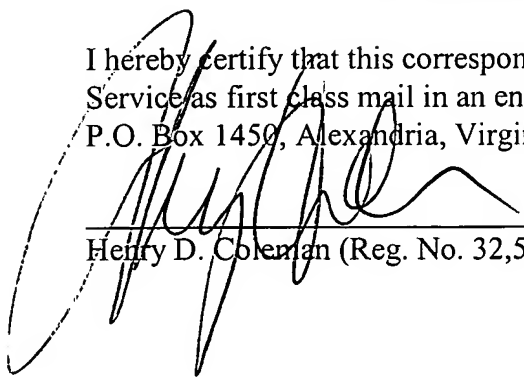
Respectfully submitted,
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Dated: September 25, 2009

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450, dated September 25, 2009.


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